



UNITED STATES DEPARTMENT OF COMMERCE

Patent and Trademark Office

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Washington, D.C. 20231

APR 21 1999

David J. Levy, Ph.D.  
Glaxo Wellcome, Inc.  
Patent Counsel  
Five Moore Drive  
Research Triangle Park, NC 27709

Re: Patent Term Extension  
Application for  
U.S. Patent No. 5,047,407

Dear Mr. Levy:

A certificate under 35 U.S.C. § 156 is enclosed extending the term of U.S. Patent No. 5,047,407 for a period of 282 days. While a courtesy copy of this letter is being forwarded to the Food and Drug Administration (FDA), you should directly correspond with the FDA regarding any required changes to the patent expiration dates set forth in the Patent and Exclusivity Data Appendix of the Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) or in the Patent Information set forth in the Green Book (FDA Approved Animal Drug Products).

Telephone inquiries regarding this communication should be directed to the undersigned at (703)306-3159.

Karin Tyson  
Senior Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 15-22  
Rockville, MD 20857

RE: EPIVIR™  
FDA Docket No.: 96E-0043

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96E-0043

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UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE EXTENDING PATENT TERM  
UNDER 35 U.S.C. § 156

PATENT NO. : 5,047,407  
ISSUED : September 10, 1991  
INVENTOR(S) : Bernard Belleau, et al.  
PATENT OWNER : BioChem Pharma Inc.  
PRODUCT : EPIVIR™ (lamivudine)

This is to certify that there has been presented to the

COMMISSIONER OF PATENTS AND TRADEMARKS

an application under 35 U.S.C. § 156 for an extension of the patent term. Since it appears that the requirements of the law have been met, this certificate extends the term of the patent for the period of

282 days

from February 8, 2009, the original expiration date of the patent, subject to the provisions of 35 U.S.C. § 41(b), with all rights pertaining thereto as provided by 35 U.S.C. § 156(b).



I have caused the seal of the Patent and Trademark Office to be affixed this 16th day of April 1999.

A handwritten signature in black ink, appearing to read "Q. Todd Dickinson", is written over the printed name.

Q. Todd Dickinson  
Acting Assistant Secretary of Commerce and  
Acting Commissioner of Patents and  
Trademarks

**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service  
Food and Drug Administration

0791 99 APR 28 11:52  
**Memorandum**

Date:

From: **Brian J. Malkin, Associate Director for Patents and Hearings**  
**Health Assessment Policy Staff (HFY-20)**

Subject: **Patent Term Restoration Application**  
**for EPIVIR<sup>TM</sup>**

To: **Dockets Management (HFA-305)**

Attached is correspondence for the docket related to the above mentioned human drug product under the Docket Number **96E-0043**. The Patent Number is **5,047,407**. Please place this recent correspondence in the appropriate file.

If you have any questions, please contact me at 827-6620. Thank you for your assistance.

Attachment